



# **Tribal LifeLine™ Project**

## **Modifying the Risk Assessment Model for Relevance to Unique Tribal Scenarios**

### **Part 2**

#### **The Risk Assessment Model**

#### **Principles and Applications**

# Cornerstones of Regulatory Decision-Making

---

## Risk-Based or Risk / Benefit – Based

- Single source, single contaminant deterministic analysis
- “Bright-line” standards apply (based on magnitude)
- Declared focus to presumed “most vulnerable” or “most exposed population
- Single point on an underlying distribution used for basis of decision (mean, 95<sup>th</sup> percentile, 99.9<sup>th</sup> percentile, Maximum, “Worst Possible Case”)

# Cornerstones of Regulatory Decision-Making

---

## Magnitude of Risk from Chem X from Source A

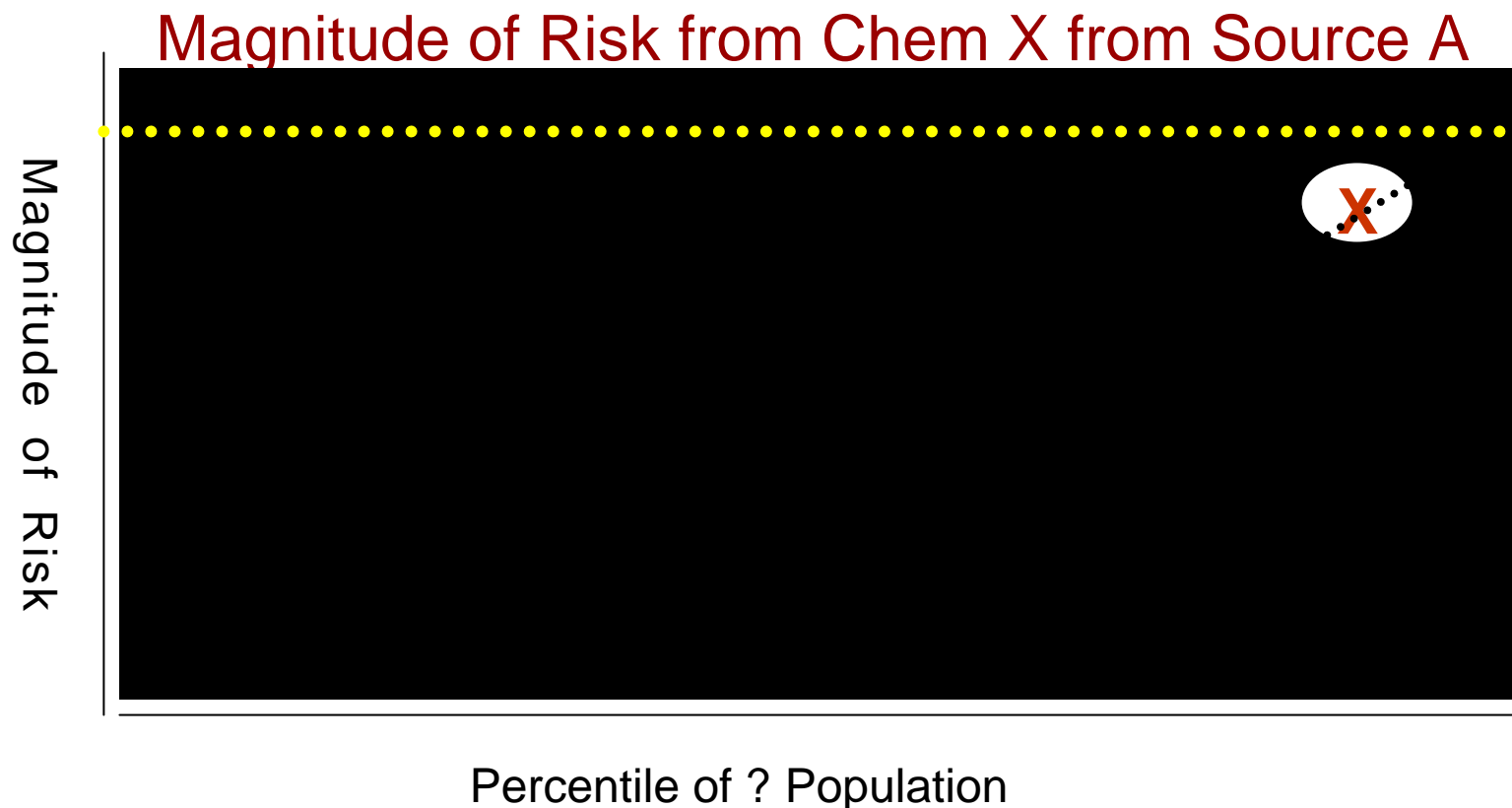
Magnitude of Risk



Percentile of ? Population

# Traditional Cornerstones of Regulatory Decision-Making

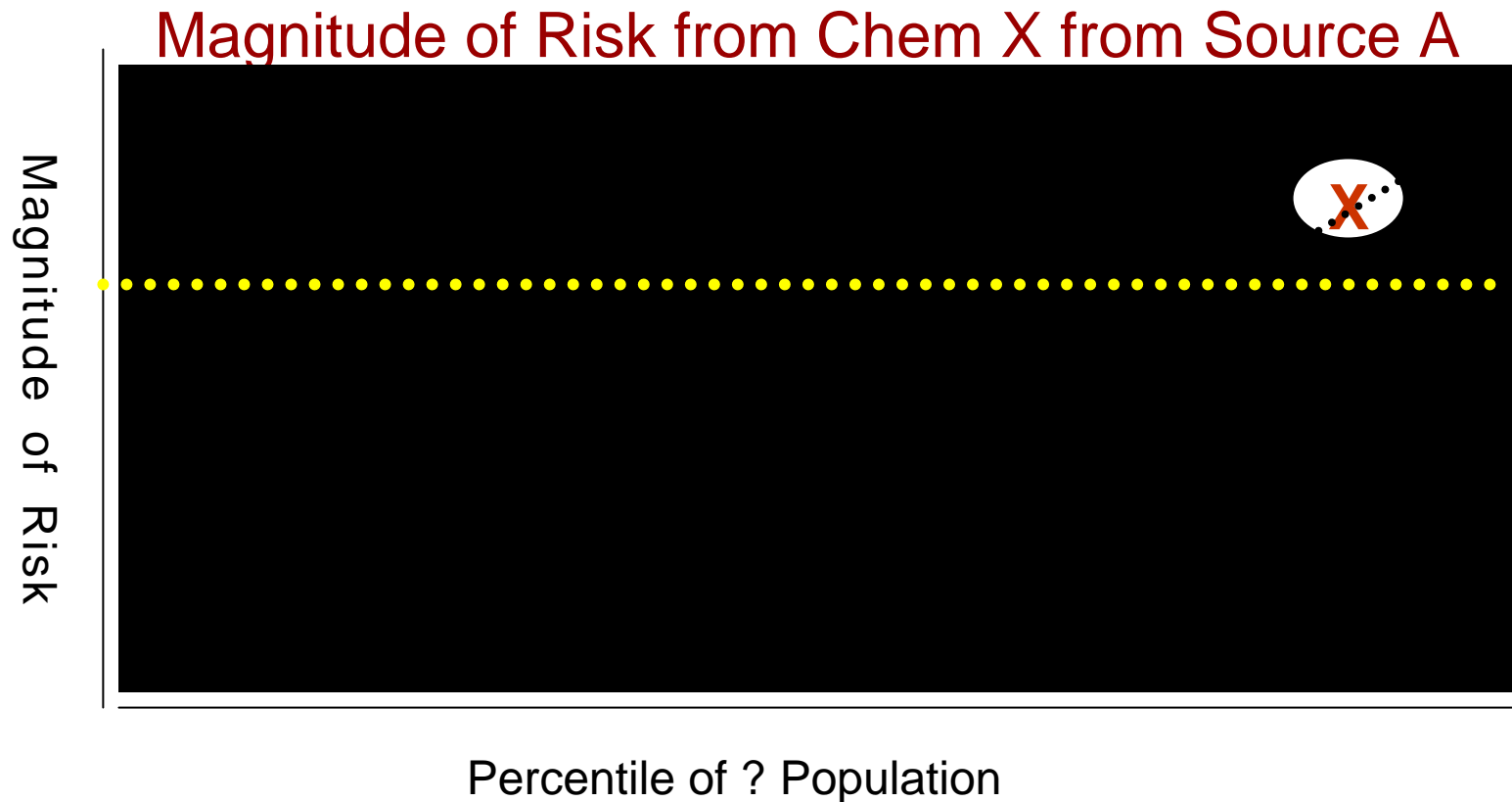
---



Is X Less Than Acceptable Risk Limit?

# Traditional Cornerstones of Regulatory Decision-Making

---

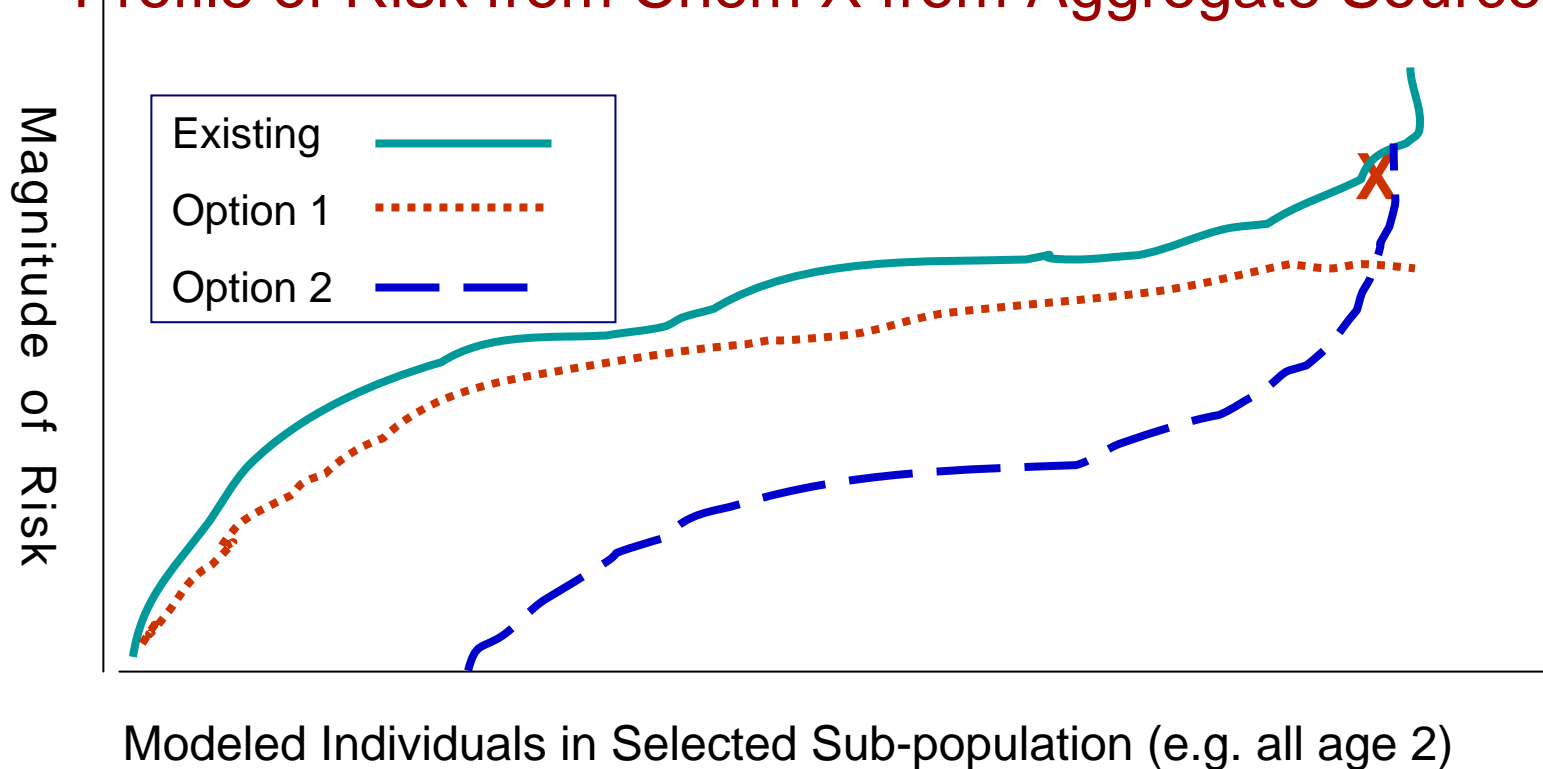


Is X More Than Acceptable Risk Limit?

# Considering the Impact of Regulatory Options

---

## Profile of Risk from Chem X from Aggregate Sources



# Objectives for New Models

---

## 1. Consider All Parameters of “Exposure and Risk”

Exposure and Risk are defined by more than Magnitude

Magnitude

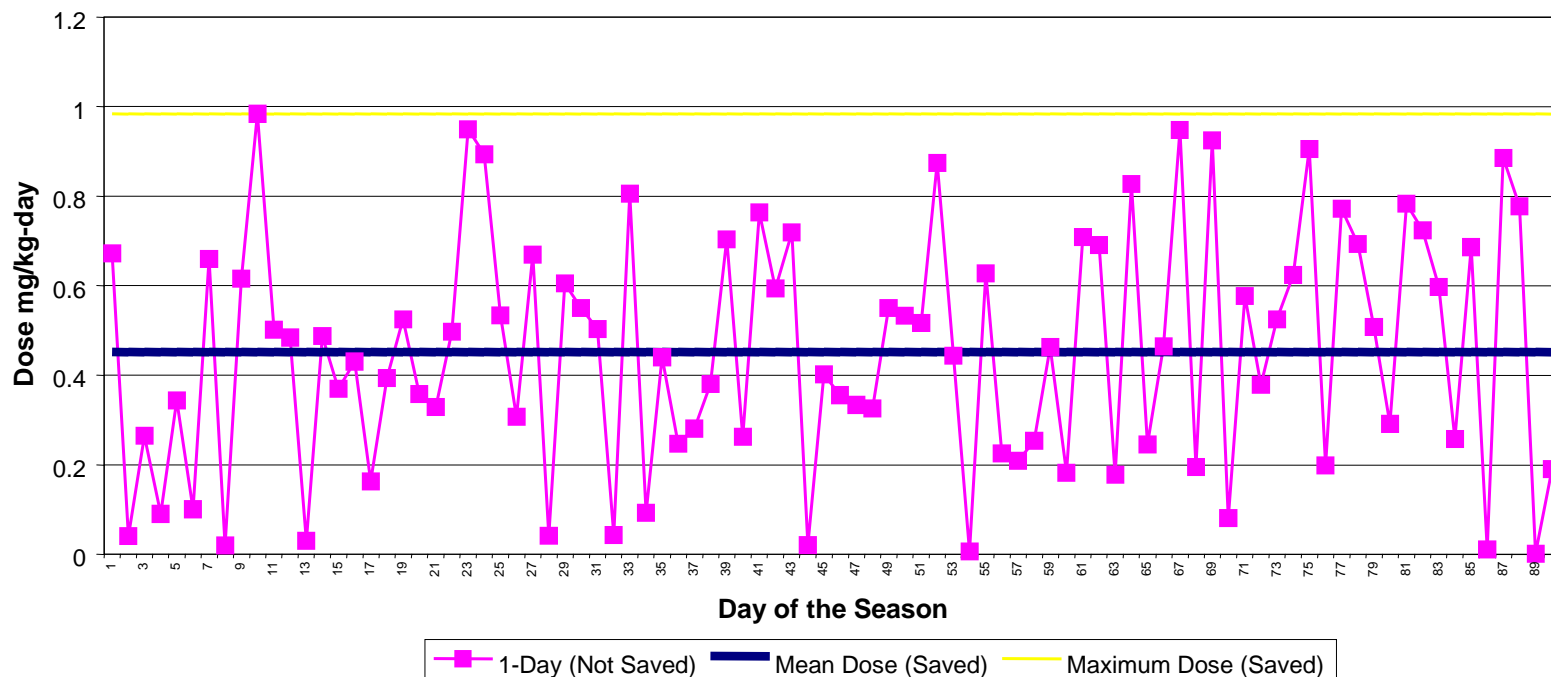
Frequency

Duration

Route

“Era of Vulnerability”

# Individual's Seasonal Maximum and Seasonal Average Exposure/Risk for Each Season in a Lifetime





# Objectives for New Models

---

- 2. Discover—not predetermine--the “most exposed/vulnerable” subpopulation**
- 3. Consider multiple sources and multiple routes of exposure**
- 4. Array the daily exposure opportunities in a longitudinal progression over life periods**

# Objectives for New Models

---

- 5. Visualize the “drivers” (important contributors) to the exposure/risk
- 5. Let the toxicology define the exposure scenario to be calculated.
- 5. Reveal the data strengths/weaknesses

# Quick Overview: Person-Oriented Modeling and MicroExposure Approaches for Aggregate/Cumulative Exposure Analysis Models

---

**= Models that Know What People DO Each Day**

**This Tells US What Opportunities They Have To Be  
Exposed !**

# Data In the LifeLine™ Model

## Describing People in the “General Population”

---

- Natality data (Birth records); National Center for Health Statistics [NCHS]
- Residential patterns;  
Current Population Statistics, US Census
- The Third National Health and Nutrition Examination Survey (NHANES III); also maintained by NCHS)
- American Housing Survey; US Census and Department of Housing and Urban Development
- National Human Activity Pattern Survey (US EPA, 1994)
- The Continuing Survey of Food Intake by Individuals (CSFII) US Department of Agriculture (USDA)

# The Fundamental Approach

---

1. Using data and assumptions, describe PEOPLE in the population of interest (physiology, where they live, what they eat, mobility, what they do)

This sets up the relationships between people and their environments—describing “opportunities for exposure”

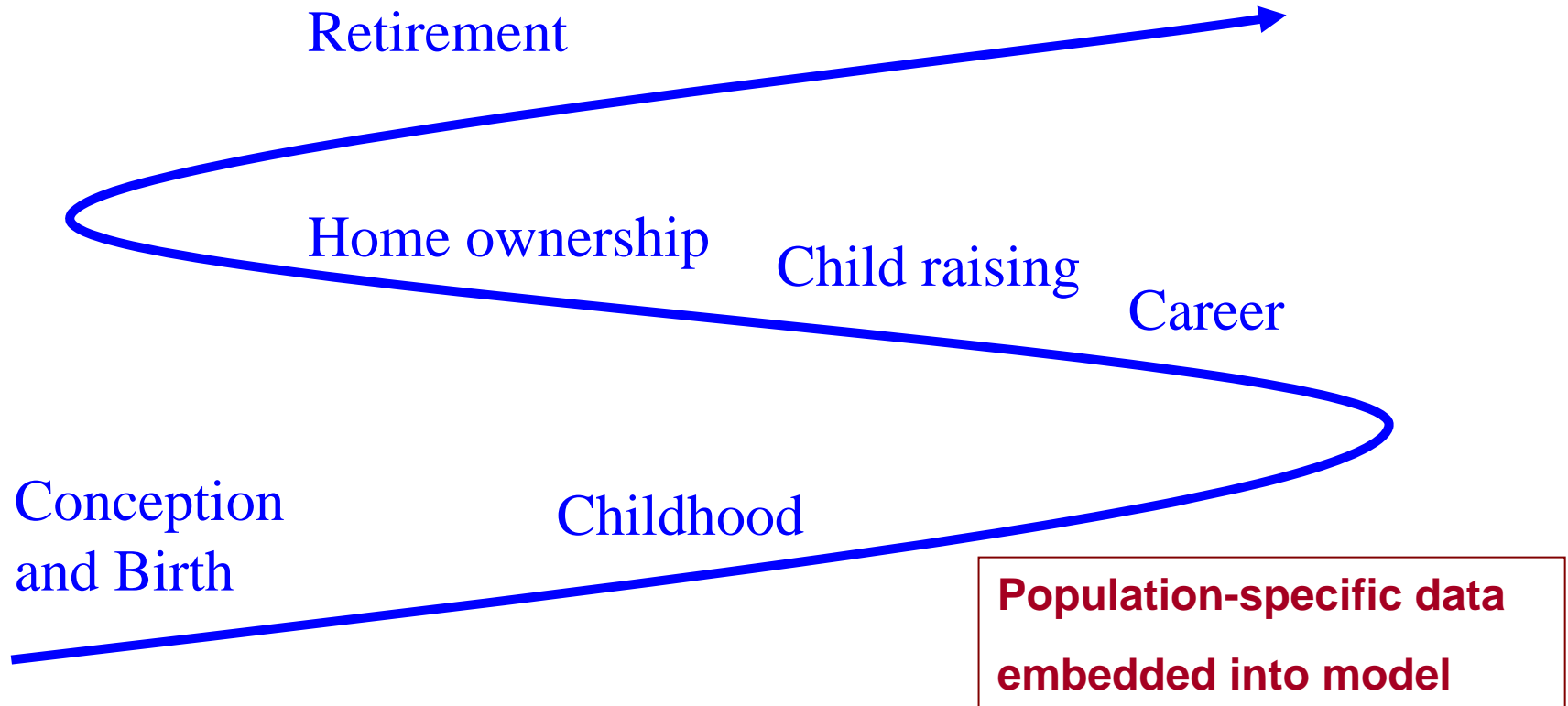
# Profiling Exposure

Going through life ➡ opportunities for exposure

[Microexposure event modeling]

Define EACH person in a population .....day by day

Gender, ethnicity, housing, activities, diet, morphometrics



# The Fundamental Approach

---

2. With chemical specific data \* supplied by the user, calculate the exposure resulting from every exposure opportunity on each day of the person's life.

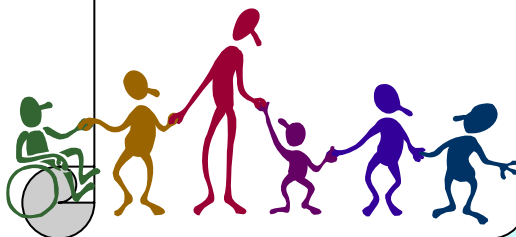
\* Data such as residues in food, in water, pesticide use, on objects in the house, on toys, clothes, furniture, pets, etc.

# The Assessor Brings Information About The Chemical of Interest

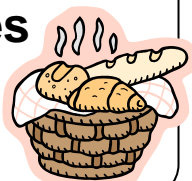
---

## Data Included in LifeLine™ Exposure and Risk Assessment Software

Age related  
height, weight/  
population  
demographics,  
birth statistics  
etc.



Dietary  
profile:  
Who eats  
what, how  
much, from  
where /  
recipes,  
food  
sources  
Etc.



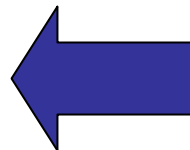
## Data Supplied by Risk Assessor

•Resides of  
chemical in  
food/water

\*Health  
hazard info.

\*Chemical  
use Info.

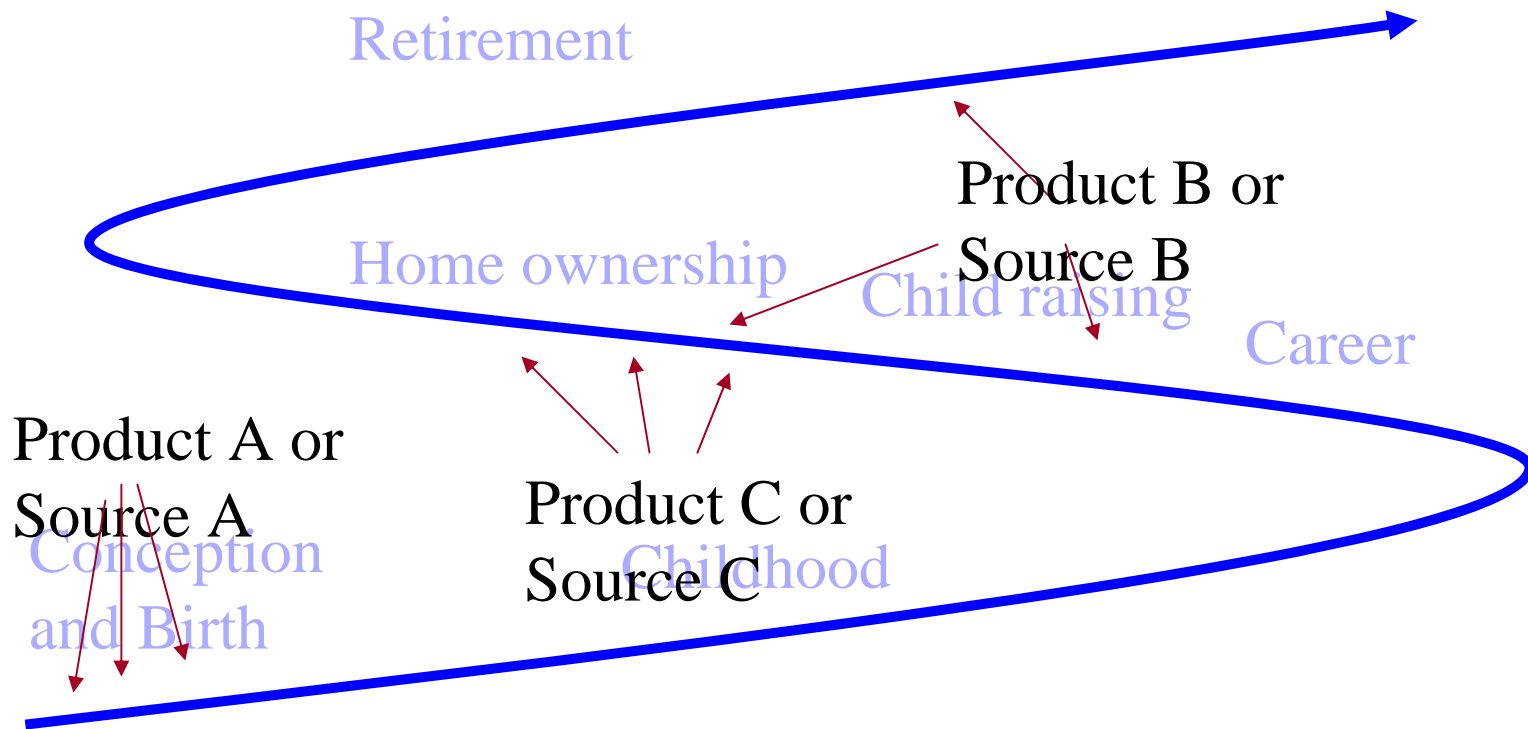
Etc.





## 2. Modeling A Person's Lifetime Exposures from Multiple Chemical Sources

---



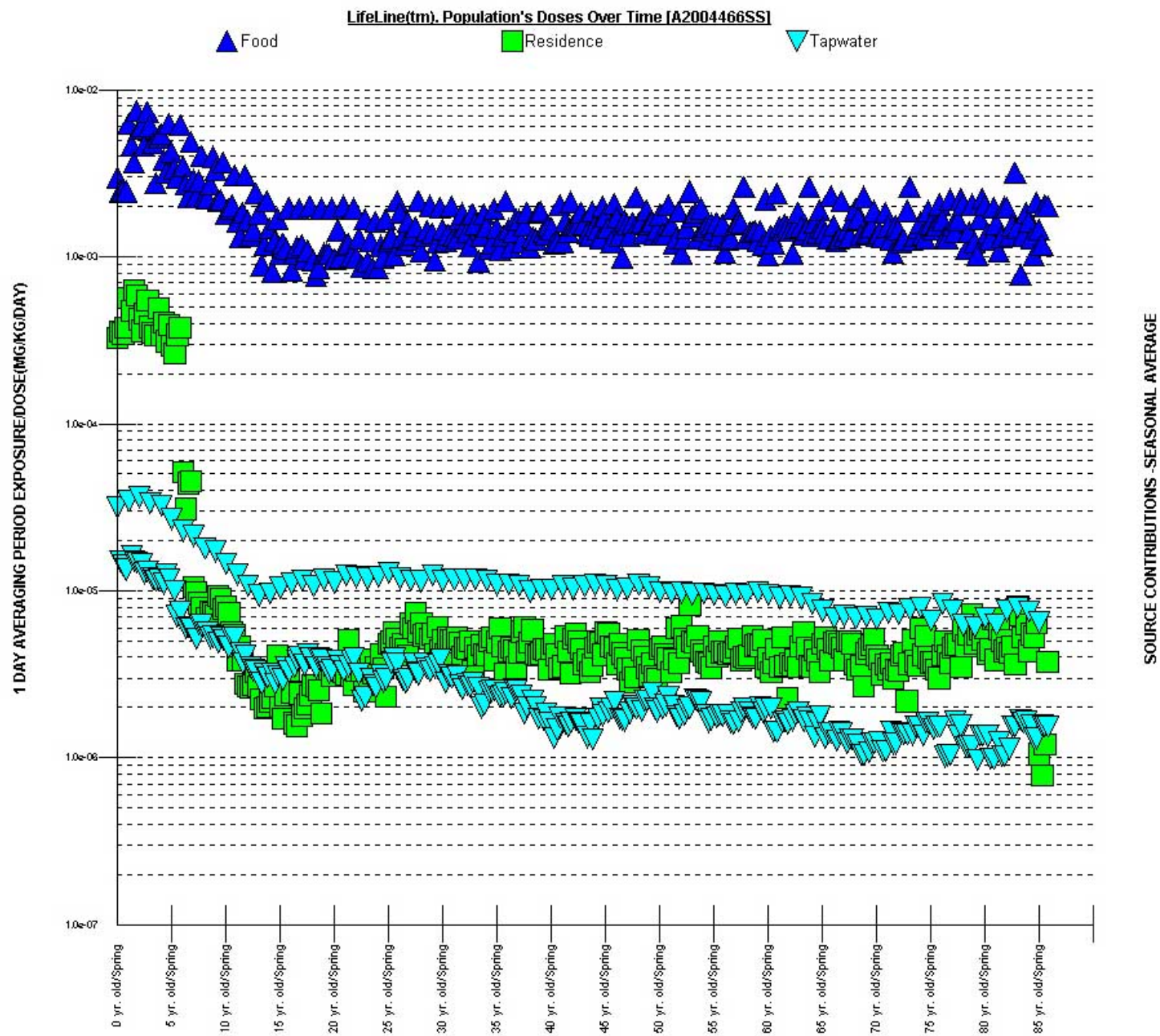
# Repeating Process Yields a Model of the Exposed Population...with Each Individual “Intact”

---

**Thousands of repetitions—each a  
new person of that population**

**Exposure data saved: by  
source, by route, by person**

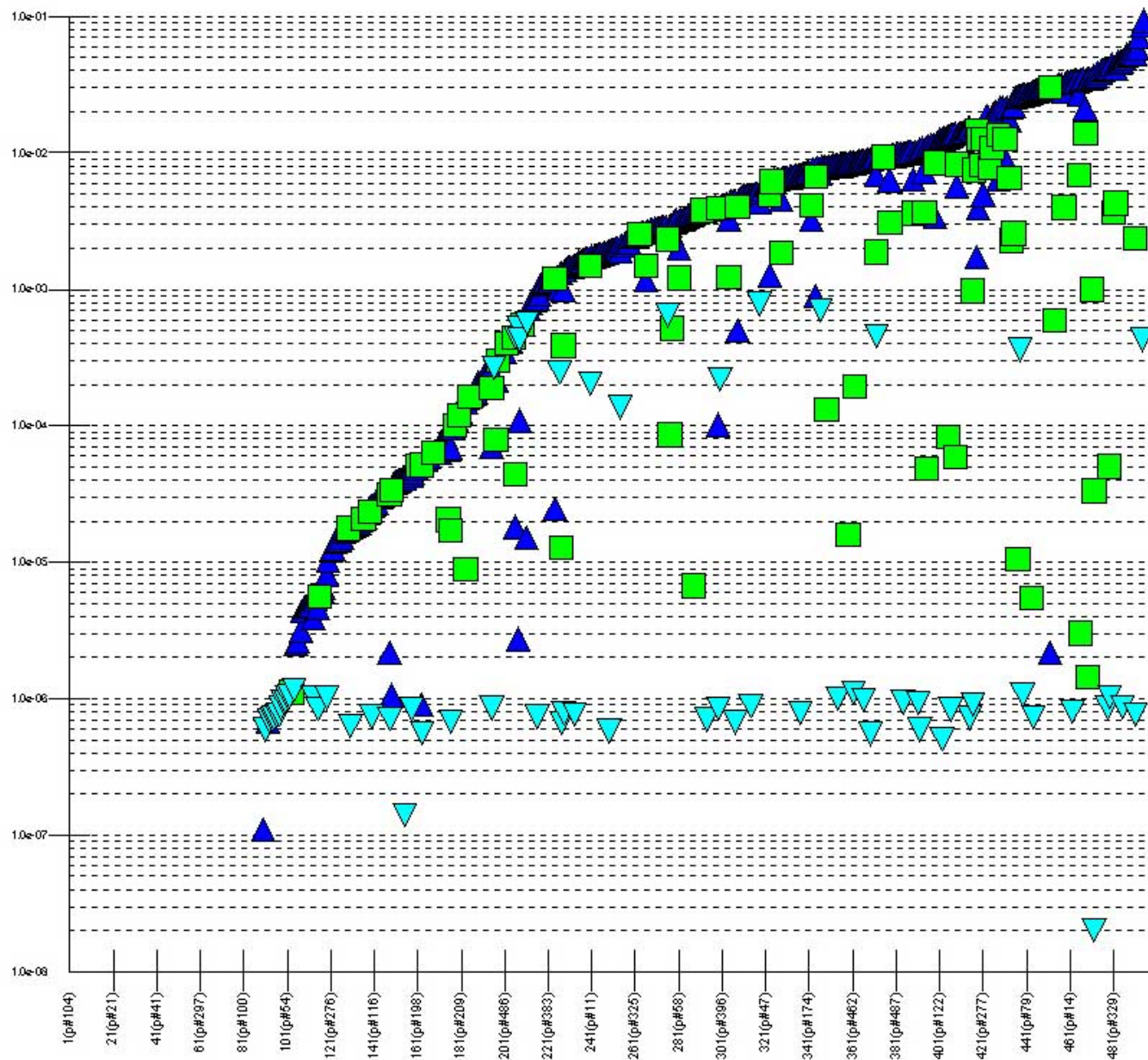
**Easily manageable with today’s  
computers / programming methods**



LifeLine(tm). Dist. of Doses at a Season and Age (Ranked by Total) [A2004466SS]

▲ Food      ■ Residence      ▼ Tapwater

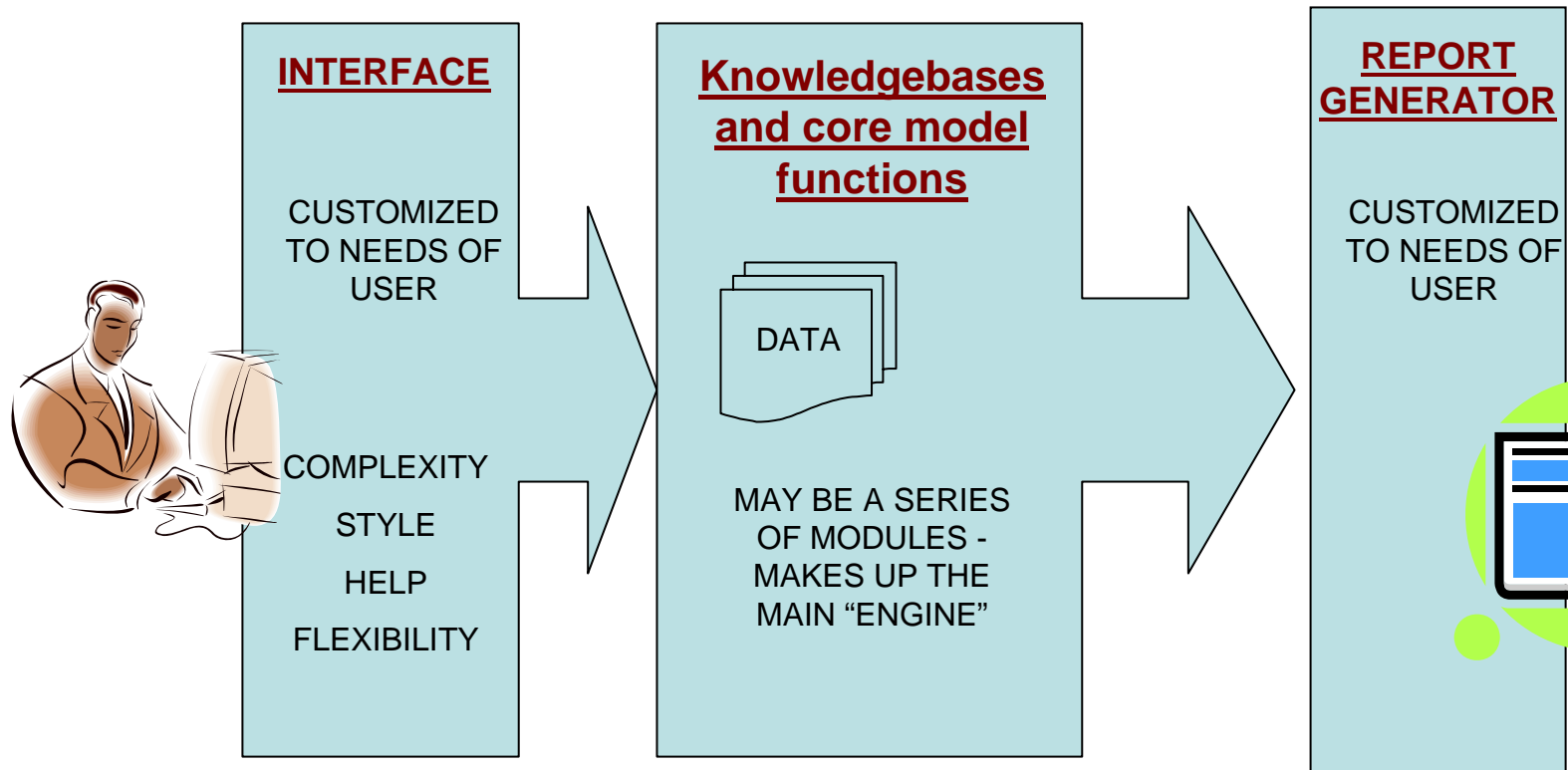
1 DAY AVERAGING PERIOD EXPOSURE DOSE (MG/KG/DAY)



SOURCE CONTRIBUTIONS - SEASONAL AVERAGE

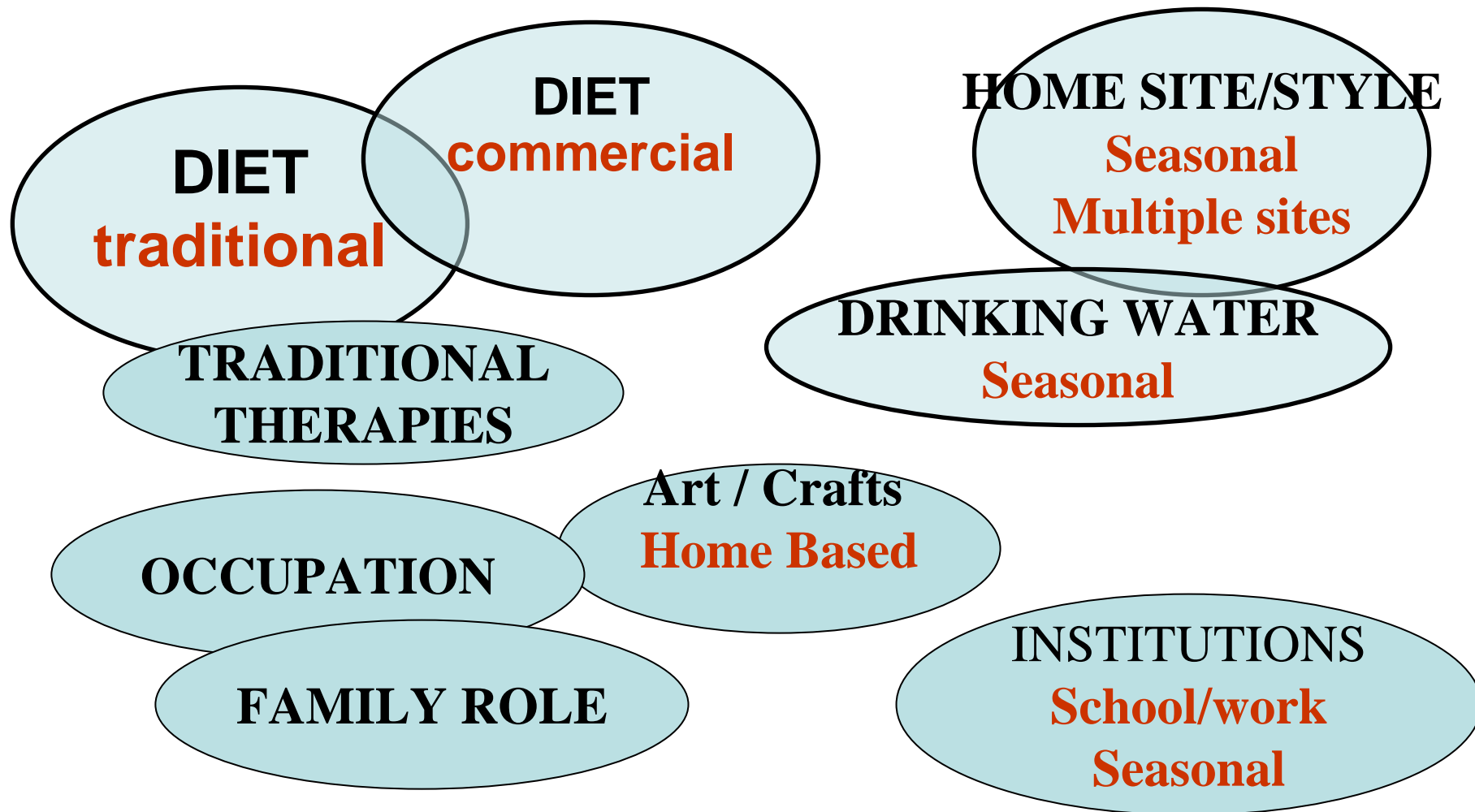
# Approach to Modeling Tribal Communities / Unique Exposure Opportunities

# Model Components (Modules)



# Exposure Scenarios Relevant to Traditional Tribal Lifestyles : Different From Lifestyles Assumed in Mainstream Exposure/Risk/Screening Models

---

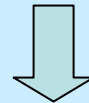
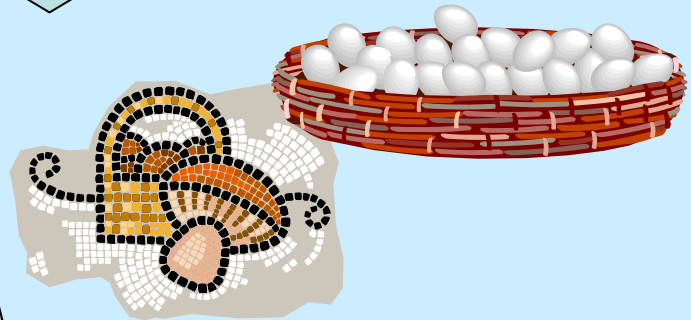
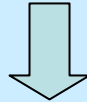
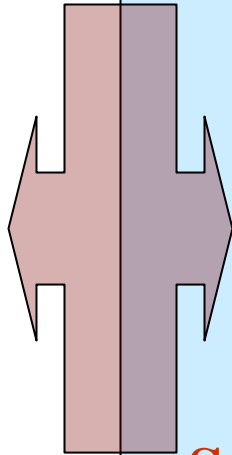


## Farm gate or Port



## Processing Industries

## Retail



**Seasonality, Age-related mix  
with commercial foods,  
storage, preparation**



## Select a Consumpt...



Select a Consumption  
Survey Set of Years

CSFII 1994 - 1998

Northern Plains

Continue



Data Set: Sub Arctic Freshwater Po

Annual Residues

Season Selected

☒ Annual

☐ Spring

☐ Summer

☐ Fall

☐ Winter

Inputs

Outputs

Translate to Food Residues

Residues Factors

	Code	Crop Group	Code	Commodity	Code	FoodForm	Residue #1 (ppm)	Residue #2 (ppm)	Residue #3 (ppm)
1	1	Berries		All		All			
2	2	Nuts		All		All			
3	3	Oil		All		All			
4	4	Shortening		All		All			
5	5	Sugar		All		All			
6	6	Fish		All		All			
7	7	Water animals		All		All			
8	8	Game mammals		All		All			
9	9	Bread		All		All			
10	10	Vegetables		All		All			
11	11	Sea mammals		All		All			
12	12	Fowl		All		All			
13	13	Egg		All		All			
14	14	Soil		All		All			
15	15	Tea/tundra		All		All			
16	16	Water		All		All			

File Edit View Season Translate Window Help

Data Set: CSFII 1994 - 1998

Annual Residues

Season Selected

☒ Annual  
☐ Spring ☐ Summer   
☐ Fall ☐ Winter

Inputs

Outputs

Translate to Food Residues

Residues Factors

	Code	Crop Group	Code	Commodity	Code	FoodForm	Residue #1 (ppm)	Resid (ppm)
11	12	STONE FRUITS		All		All		
13	13	BERRIES	550	Blackberry		All		
14	13	BERRIES	560	Blackberry, juice		All		
15	13	BERRIES	561	Blackberry, juice - babyfood		All		
16	13	BERRIES	570	Blueberry		All		
17	13	BERRIES	571	Blueberry- babyfood		All		
18	13	BERRIES	580	Boysenberry		All		
19	13	BERRIES	1360	Currant		All		
20	13	BERRIES	1370	Currant, dried		All		
21	13	BERRIES	1420	Dewberry		All		
22	13	BERRIES	1490	Elderberry		All		
23	13	BERRIES	1740	Gooseberry		All		
24	13	BERRIES	1910	Huckleberry		All		
25	13	BERRIES	2080	Loganberry		All		
26	14	TREE NUTS		All		All		
27	15	CEREAL GRAINS		All		All		
28	18	NONGRASS ANIMAL		All		All		
29	19	HERB AND SPICES		All		All		
30	21	BEEF		All		All		
31	23	GOAT		All		All		
32	24	HORSE		All		All		
33	25	PORK		All		All		
34	26	SHEEP		All		All		
35	27	MILK		All		All		
37	28	GAME	2210	Meat, game		All		
38	29	RABBIT		All		All		
39	40	CHICKEN		All		All		



Data Set: Sub Arctic Freshwater Pe

Annual Residues

Season Selected

☒ Annual

☐ Spring

☐ Summer

☐ Fall

☐ Winter

Inputs

Outputs

Translate to Food Residues

Residues Factors

	Code	Crop Group	Code	Commodity	Code	FoodForm	Residue #1 (ppm)	Residue #2 (ppm)
1	1	Berries		All		All		
2	2	Nuts		All		All		
4	3	Oil	7	seal		All		
5	3	Oil	8	beluga		All		
6	3	Oil	9	oogruk (bearded seal)		All		
7	3	Oil	10	walrus		All		
8	3	Oil	11	whale		All		
9	3	Oil	12	corn		All		
10	4	Shortening		All		All		
11	5	Sugar		All		All		
12	6	Fish		All		All		
13	7	Water animals		All		All		
15	8	Game mammals	36	caribou		All		
16	8	Game mammals	37	beef		All		
17	8	Game mammals	38	bear		All		
18	8	Game mammals	39	beaver		All		
19	8	Game mammals	40	deer		All		
20	8	Game mammals	41	mink		All		
21	8	Game mammals	42	moose		All		
22	8	Game mammals	43	muskrat		All		
23	8	Game mammals	44	rabbit		All		
24	8	Game mammals	45	squirrel		All		
25	8	Game mammals	46	elk		All		
26	9	Bread		All		All		
27	10	Vegetables		All		All		
28	11	Sea mammals		All		All		
29	12	Fowl		All		All		



Data Set: Sub Arctic Freshwater Pe

Annual Residues

Season Selected

☒ Annual

☐ Spring

☐ Summer

☐ Fall

☐ Winter

Inputs

Outputs

Translate to Food Residues

Residues Factors

	Code	Crop Group	Code	Commodity	Code	FoodForm	Residue #1 (ppm)	Residue #2 (ppm)
17	8	Game mammals	38	bear		All		
18	8	Game mammals	39	beaver		All		
19	8	Game mammals	40	deer		All		
20	8	Game mammals	41	mink		All		
21	8	Game mammals	42	moose		All		
22	8	Game mammals	43	muskrat		All		
23	8	Game mammals	44	rabbit		All		
24	8	Game mammals	45	squirrel		All		
25	8	Game mammals	46	elk		All		
26	9	Bread		All		All		
27	10	Vegetables		All		All		
30	11	Sea mammals	65	beluga	25	flesh		
31	11	Sea mammals	65	beluga	26	liver		
32	11	Sea mammals	65	beluga	33	eyes		
33	11	Sea mammals	65	beluga	34	flipper		
34	11	Sea mammals	65	beluga	35	skin and fat (muktuk)		
35	11	Sea mammals	66	seal		All		
36	11	Sea mammals	67	oogruk		All		
37	11	Sea mammals	68	walrus		All		
38	11	Sea mammals	69	whale		All		
39	11	Sea mammals	70	devilfish (gray whale)		All		
40	12	Fowl		All		All		
41	13	Egg		All		All		
42	14	Soil		All		All		
43	15	Tea/tundra		All		All		
44	16	Water		All		All		





Data Set: Sub Arctic Fresh

Processing Factors for all

Season Selected

There is no season chosen for processing factors.

Inputs  
Outputs  
☐ Use probability factors  
☒ Processing factors

Translate to Food Residues

Residues Factors

	Code	Crop Group	Code	Commodity		Heating	Refining	Storage	Other
1	1	Berries		All	All				
2	2	Nuts		All	All				
4	3	Oil	7	seal	All				
5	3	Oil	8	beluga	All				
6	3	Oil	9	oogruk (bearded seal)	All				
7	3	Oil	10	walrus	All				
8	3	Oil	11	whale	All				
9	3	Oil	12	corn	All				
10	4	Shortening		All	All				
11	5	Sugar		All	All				
12	6	Fish		All	All				
13	7	Water animals		All	All				
14	8	Game mammals		All	All				
15	9	Bread		All	All				
16	10	Vegetables		All	All				
17	11	Sea mammals		All	All				
18	12	Fowl		All	All				
19	13	Egg		All	All				
20	14	Soil		All	All				
21	15	Tea/tundra		All	All				
22	16	Water		All	All				

## Analysis Preferences

General Dietary Averaging Period/Toxic Hazard Tribal

## Seasonal mobility

☒ Enable seasonal mobilityFraction of tribe  
participating in move:

75

Season moved:

Summer

## Health related parameters

☒ Enable health impactFraction of tribe with health  
related issues:

20

Increase in breathing rate  
(m3/day):

10

## Cultural blending

☒ Enable cultural blending

Survey: Sub Arctic Freshwater Perimeter

Fraction at primary residence:

70

Fraction at seasonal residence:

30

## Environmental exposures

Fraction private water supply:

100

OK

Cancel

ACER

PRIN

Control Panel

Shared Documents

Chris's Documents

rttapwaterconcentry  
rttapwaterconcentry MEC ApprtVerifyReg.dll  
1.0.0.1

## Sweat Lodges: Open Fire or Hot Stone







# End Use Product Equivalent Application Method Wizard

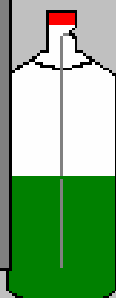


Your Active Ingredient

Your product name

Burned/Sweat Lodge

*Application Method Description*

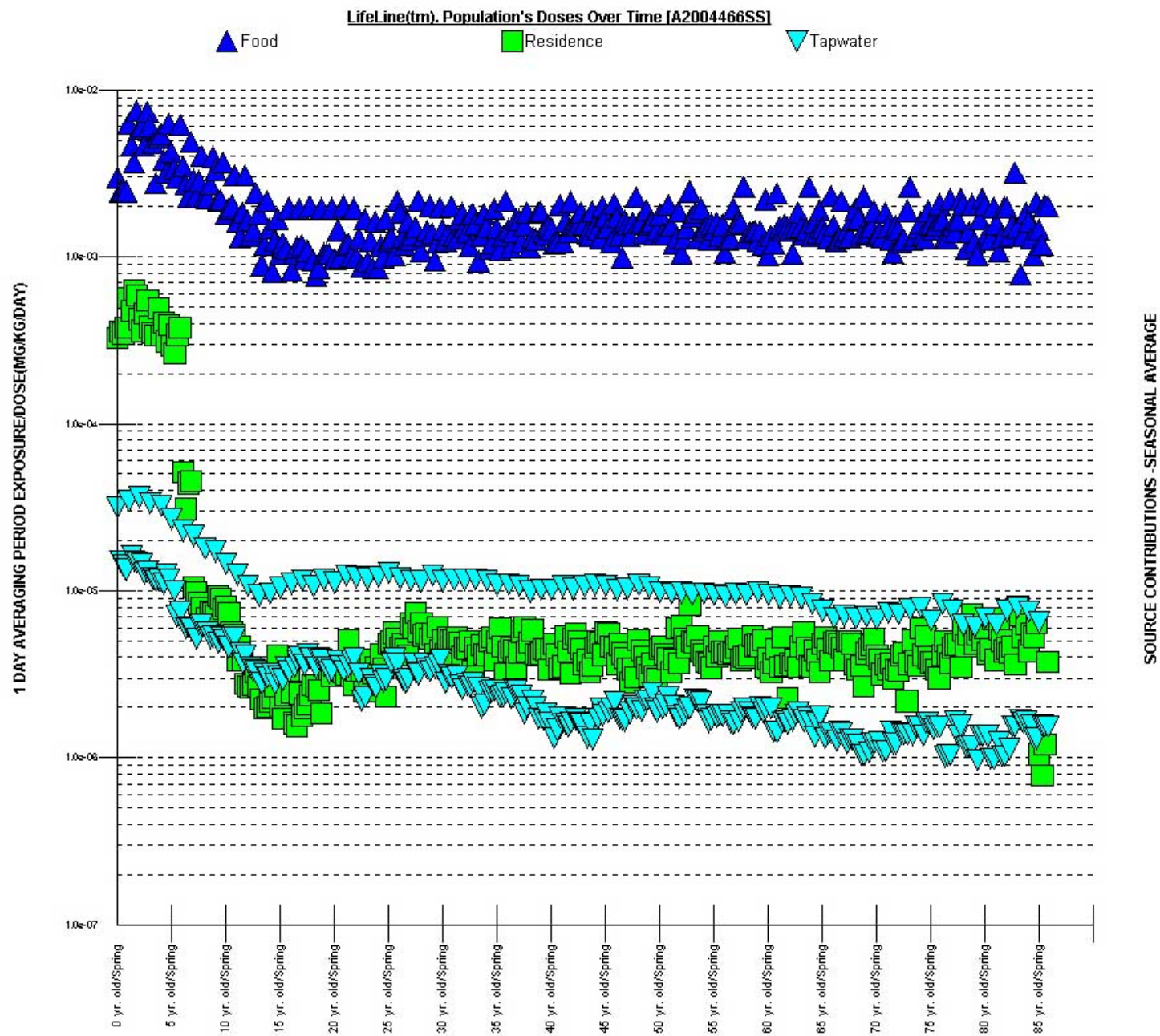


Start Age	End Age	Daily Probability	Duration Point Estimate	Sweat Lodge Duration	Max	Min	# of Points
Group One:							
0	15	0.4	<input checked="" type="radio"/> 120	<input type="radio"/>	0	0	0
Group Two:							
16	35	.8	<input checked="" type="radio"/> 160	<input type="radio"/>	0	0	0
Group Three:							
36	85	.83	<input checked="" type="radio"/> 145	<input type="radio"/>	0	0	0
Group Four:							
0	0	0	<input type="radio"/> 0	<input type="radio"/>	0	0	0
Group Five:							
0	0	0	<input type="radio"/> 0	<input type="radio"/>	0	0	0

< Back

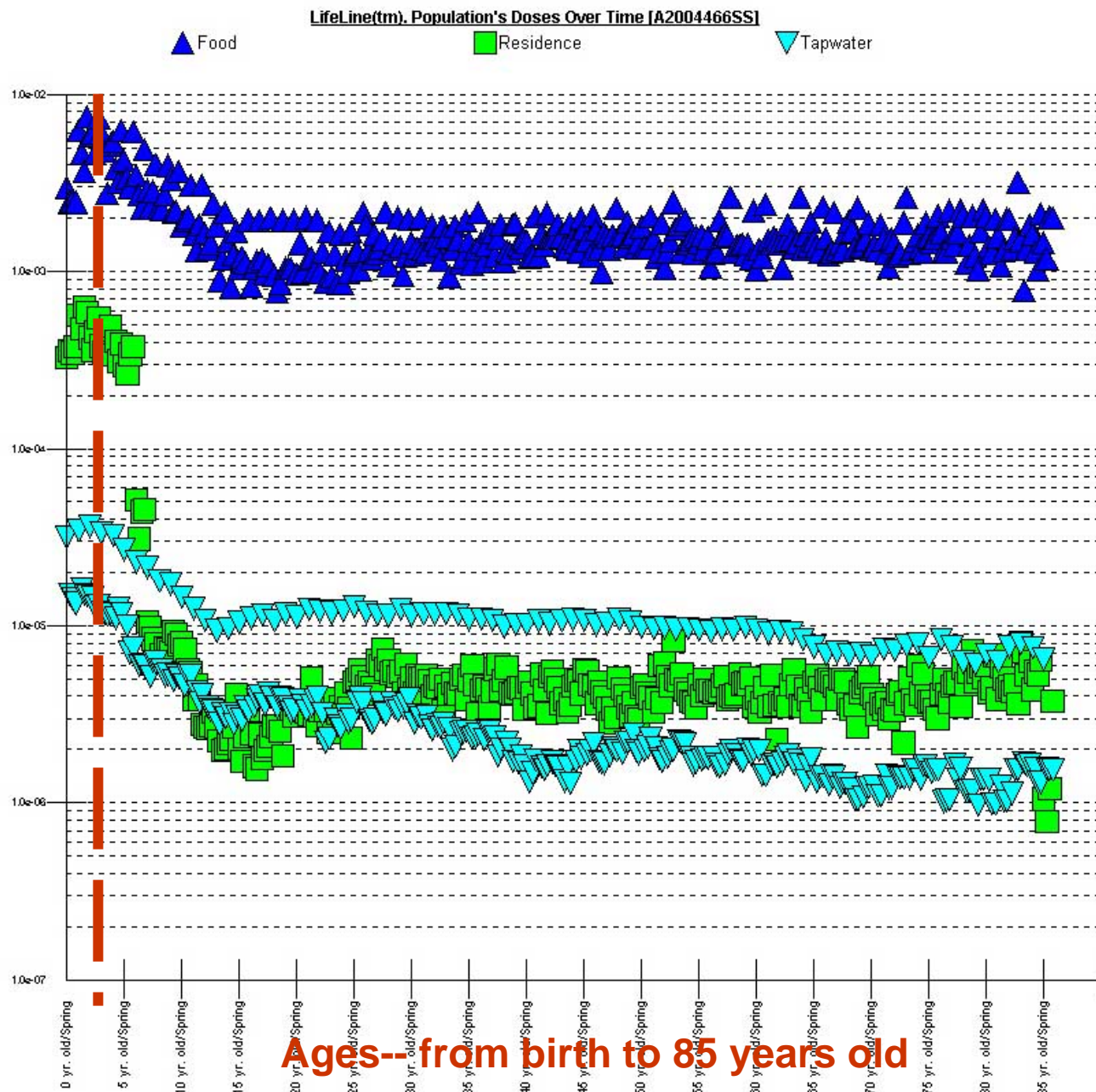
Next >

Cancel



# Risk Reduction Exposure

1 DAY AVERAGE DOSE PERIOD (EPA/AGD)



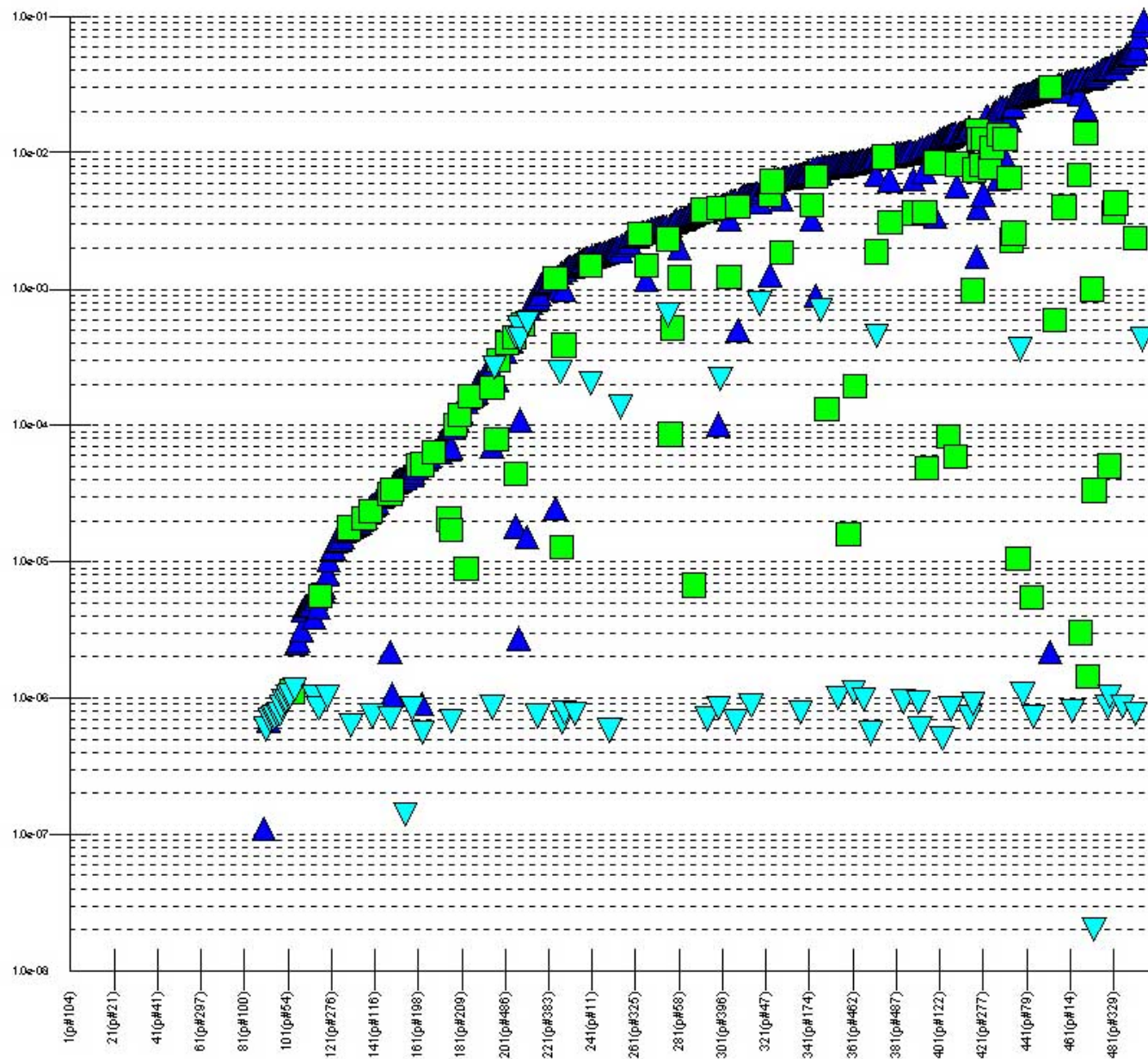
SOURCE CONTRIBUTIONS - SEASONAL AVERAGE

Ages-- from birth to 85 years old

LifeLine(tm). Dist. of Doses at a Season and Age (Ranked by Total) [A2004466SS]

▲ Food      ■ Residence      ▼ Tapwater

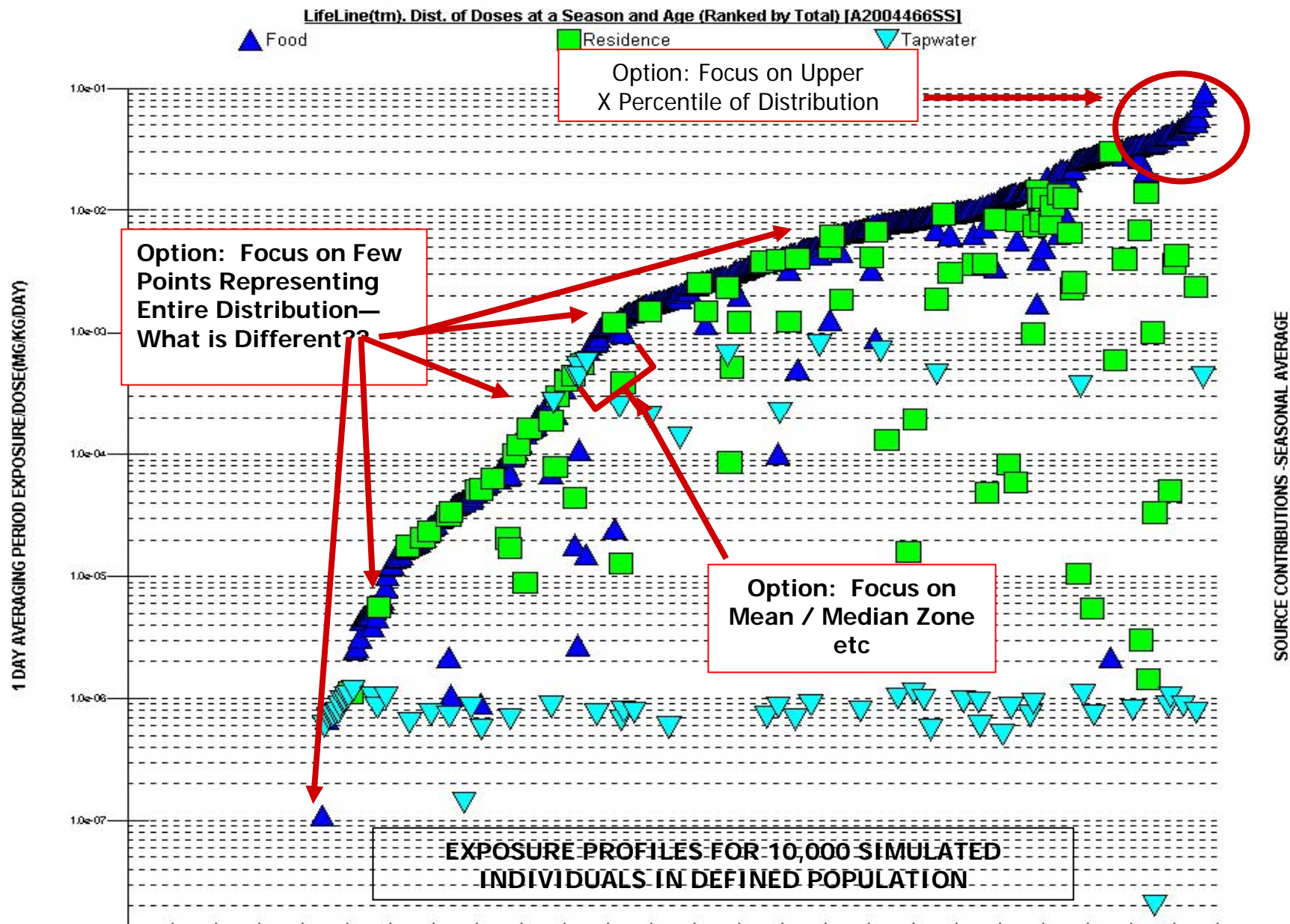
1 DAY AVERAGING PERIOD EXPOSURE DOSE (MG/KG/DAY)



SOURCE CONTRIBUTIONS - SEASONAL AVERAGE



# Options for Decision Making



# Important Points to Consider

---

1. This is a TOOL relevant to US Legislative “risk based” regulation -- but does not inhibit conversation about other Tribal philosophies
2. Project “process” accepts tribal traditions and attitudes
3. Needs for training at the tribal level and at the federal level (application of relevant assumptions and analysis options)
4. Model available to all- provides tool for tribes and their risk assessors / public health professionals
5. **Objective: Making the tribal communities “visible” for risk-based decision making—including at the local level.**

# Existing Functional Capacities in LifeLine™ Core Modules

---

- **Probabilistic approach** to calculation of exposure and risk -- provides a distribution of answers for the assessor to consider – maximum exposure, average exposure, exposure at the 95th, 99th , 99.9th, or any other percentile of the subject population
- **Use of single values or full distributions** of residue values as input to the analysis
- **Aggregation of exposures from multiple sources**, and reporting of total exposures as well as reporting of exposure from each contributing source (drinking water, showering, swimming, etc.)
- **Aggregation of exposures from multiple routes**, and reporting of total exposures as well as reporting of exposure from each contributing route (oral, dermal, inhalation)

# Existing Functional Capacities in LifeLine™ Core Modules

---

- use of **seasonally specific data** across the yearly spectrum
- consideration of particular **age groups** or other **subpopulations of interest**
- Presentation of exposure reports or risk reports using **multiple toxicology endpoints** appropriate for different exposure periods (acute, intermediate term, long term or lifetime)
- **Illustrative graphics and exportable files** for use in other software programs at the user's discretion.
- **Water residue input capabilities** for bottled water, tap water, direct and indirect water.



# Existing Functional Capacities in LifeLine™ Core Modules

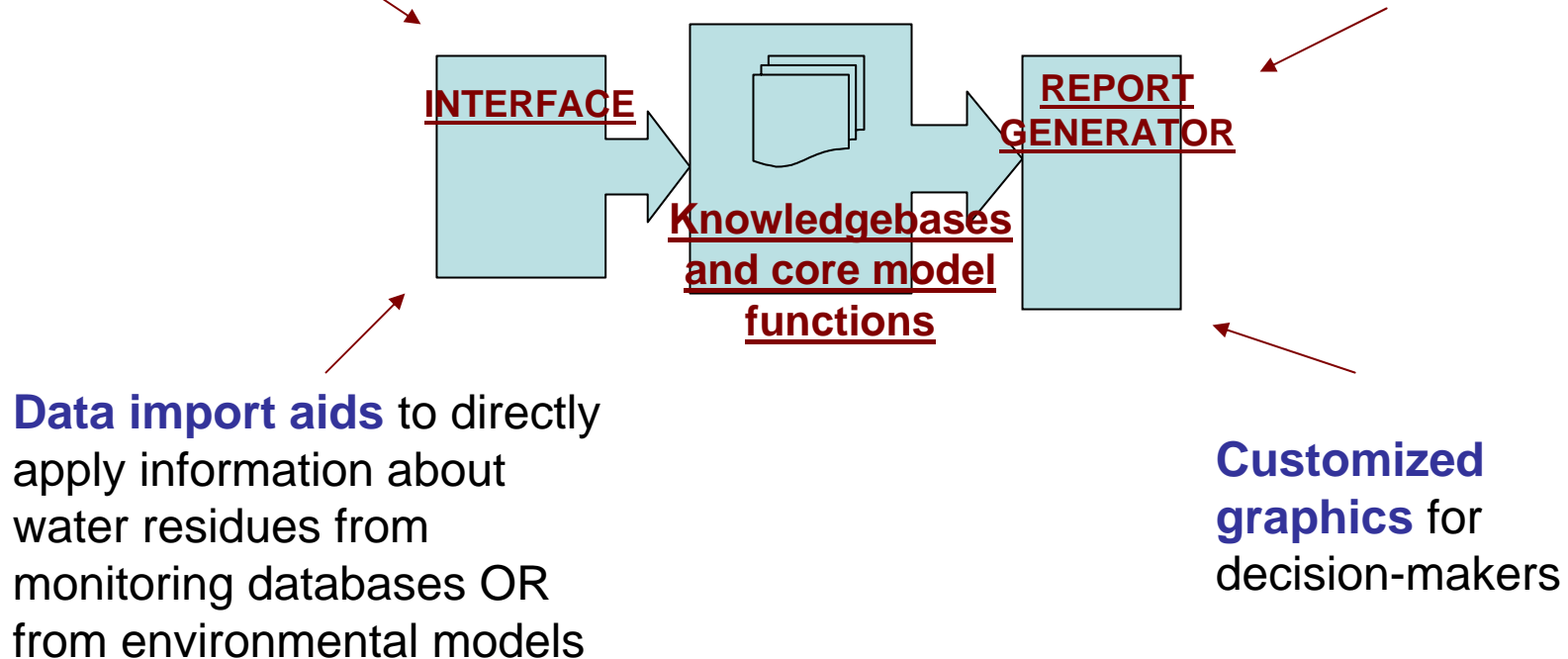
---

- **Transparency** of model operation and underlying data
- **Many rounds of evaluation** by the EPA Science Advisory Panel, Board and other State and academic review mechanisms
- **TRIBAL LIFELINE™ MODEL**
  - Customized databases – eg. traditional diets, housing, activity profiles
  - New functions – “cultural blending”, seasonal definitions, health-related changes in activity patterns, etc.

# Potential New Capacities in Core Modules

Automated interfaces and **User Tutorials** to facilitate learning the model operations

Exposure and risk assessment **reports tailored** to the regulatory requirements (or traditions) of the Office of Water



# Proposed Customizations for OW

---

## **FOCUS ON INTERFACE:**

- Facilitate learning model features/functions while actually doing analysis tasks
- Make relevant to OW experiences/mission/needs

## **Modifications:**

- Provide a sequential “guide” which automatically takes the user through the processes of entering data, setting analysis specifications and choosing report options.
- Modify interface to easily accommodate information relevant to any chemical agent, not just those resulting from pesticide use.

# Tribal LifeLine™ Project

---

[www.TheLifeLineGroup.org](http://www.TheLifeLineGroup.org)

- Dr. Christine Chaisson
  - (toll free)1- 877-978-6496
  - P: 703-978-6496
  - F: 703 978-6962
  - [CFChaisson@TheLifeLineGroup.org](mailto:CFChaisson@TheLifeLineGroup.org)
- Elizabeth Resek
  - EPA Office of Science Coordination  
Coordinator and Policy
  - Office of Prevention, Pesticides and  
Toxic Substances
  - P: 202 564-8459
  - F: 202 564-8452
  - [Resek.Elizabeth@epa.gov](mailto:Resek.Elizabeth@epa.gov)
- Dr. Claire Franklin
  - P: 613 xxxxxxxx
  - [CAFranklin@TheLifeLineGroup.org](mailto:CAFranklin@TheLifeLineGroup.org)
- Karen Rudek
  - EPA Tribal Programs  
Office of Water
  - P: 202 564-0472
  - F: 202 564-0480
  - [Rudek.Karen@epa.gov](mailto:Rudek.Karen@epa.gov)